



**PTWS Series
Dissolution Test Instrument**

Operation Qualification (OQ)

Version 1.0

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Section 1.0 Scope Introduction

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Introduction

Objective

Operational qualification (OQ) is the process by which all functions of the Pharma Test PTWS x20 instrument are being validated. For all tests performed, the results are recorded and the pass/fail evaluation of all tests is determined by comparing the results with pre-determined acceptance limits. The procedure used to certify performance and any certified/accredited procedure that forms the test and certification of the equipment will be identified and/or included in the protocol.

Equipment

The Pharma Test PTWS x20 Dissolution Instrument is composed of:

- PTWS x20 dissolution testing instrument
- All required accessories
- Options supplied as specified by customer

The PTWS x20 Dissolution Tester contains eight sample vessels and eight stirrer positions. It is used for the dissolution testing of a variety of pharmaceutical compounds including; tablets, capsules, transdermal patches and membranes. The PTWS x20 can be used in several configurations that satisfy USP criteria e.g. rotating baskets or paddles (USP Apparatus 1 and 2), paddles over disk (USP Apparatus 5) and rotating cylinder for transdermal applications (USP Apparatus 6). The PTWS x20 is supplied with a thermostatically controlled water heater/circulator system. The heater temperature can be controlled by the PTWS x20 as are all other operating parameters such as paddle speed.

Tablet (capsule) can be dropped into the vessel sequentially. The Pharma Test dissolution tester PTWS x20 is designed of two major instruments, the drive and heating system which is connected to the water bath and separated from the drive to prevent vibration transfer into the vessels.

A run time protocol can be printed, when the PT-RP80 report printer or any Pharma Test dissolution software is used with the instrument. The temperature sensing probe measures and records the actual temperature of the water bath. Temperature readings can be taken before, after, and periodically during a run to ensure complete compliance throughout the run by using an external certified thermometer. Bath temperature readings are displayed on the screen of the PTWS x20 dissolution instrument.

Optional installation accessories for the PTWS x20 are:

- TM-x20 manual tablet drop magazine
- TMA-x20 automated tablet drop magazine
- EPE-x20 movable, automated sampling system (requires TM-x20 or TMA-x20)
- ITM-x20 individual media temperature monitoring device

Instructions for Documentation Completion

All performers and reviewers must complete qualification forms using the following guidelines:

Complete all items on a form in full.

Document any deviation from defined protocols and accepted results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.

Write additional comments on an addendum sheet when there is not enough space on a form to accommodate all comments. Follow these three steps when adding an addendum sheet:

1. Write down your initials
2. Write down the date of the additions
3. Number the addendum pages alphanumerically
4. Insert the addendum sheet behind the original page
5. Make all entries in permanent ink.

Correcting Entries

If you need to make corrections on a form, use the procedures described below:

Correcting Short Entries

To correct a short entry (such as a single word or test result) on a form follow this procedure:

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write down the correction to the upper right of the original entry
3. Give a brief explanation of the change
4. Write down your initial
5. Write down the date of the change

Correcting Long Entries

To correct a long entry or information block on a form follow this procedure:

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write the correction on a separate addendum sheet
3. Give a brief explanation of the change.
4. Write down your initial
5. Write down the date of the change
6. Number the addendum pages alphanumerically
7. Insert the addendum sheet behind the original page

Marking Elements That Are Not Applicable

Some elements may not apply to your system's configuration. The elements that are not required may be a procedure or part of a procedure and/or a form or part of a form. Mark each element carefully according to the instructions below, so that it will be clear that the element is unnecessary and that you have not skipped or forgotten the element.

1. Draw a diagonal line, bottom left to upper right corner, through the element that is not required
2. Write down the letters "NA" (for "Not Applicable"), your initials, and the current date above the line
3. Include comments above the line or on the form to document the reason the element is not required
4. Where NA is indicated as an option, check this field
5. Mark the section "rec." (for "received") if the part has been identified
6. Mark the section "miss." (for "missing") if the part has not been identified and needs to be sent immediately to finish the installation; in that case make sure that the missing part has been ordered by you and has been confirmed by us for shipment

The performer and reviewer must sign and date all forms as usual, even when part or all of the form is marked "NA".

NOTE: All original entries must remain legible after any corrections have been made.

Conditions Requiring Re-Qualification

CAUTION: The following conditions require re-qualification:

- When a system modification has been completed which affects the installation qualification
- When this system is being removed from where it was originally installed

Re- calibration/ Re-certification Requirements

The following conditions require Operation Qualification (OQ) re-calibration/re-certification:

- When the software or firmware has been upgraded or changed
- A pre-determined period of time or use has passed
- After any minor service has been done
- After any parts have been replaced
- When this system is being removed from where it was originally installed

Operation Qualification Program

This document is divided in sections.

Section 1.0 Scope Introduction

This section explains the purpose and use of this document and the general operation qualification procedure.

Section 2.0 Instrument Identification

This section has the purpose of identifying the instrument at hand, including parts and accessories, required documentation, and installation site requirements.

Section 3.0 Equipment Description

In this section the equipment in this system, the required documentation and side installation requirements are identified.

Section 4.0 Personnel Identification

In this section the user of the equipment, the equipment required for qualification is identified and the end user information is written down to complete the qualification.

Section 5.0 Operation Qualification Procedure

This section contains the operation qualification procedure, test protocols and test results in a pass/fail format for each test. Where accreditation is held for the calibration of the equipment being qualified, this procedure will be referenced. Where applicable, copies of these procedures are available from Pharma Test upon request.

Section 6.0 Result and Comments

This section is used to document the result of the installation and for comments regarding the installation procedure.

Section 2.0 Instrument Identification

Check if the PTWS x20 according to the completed IQ is present. Enter the serial number of the instrument. The serial number is printed on the type plate on the back of the instrument:

Part-No.	Instrument Description	Type	OK	N/A	Serial No.
30-41000	Dissolution Testing Instrument	PTWS 120D			
30-41100	Dissolution Testing Instrument	PTWS 120S			
30-48000	Dissolution Testing Instrument	PTWS 820D			
30-46000	Dissolution Testing Instrument	PTWS 620			
30-41200	Dissolution Testing Instrument	PTWS 1220			
30-46600	Dissolution Testing Instrument	PTWS D620			

Performed by: _____
Signature

Date: _____
MM/DD/YYYY

Section 2.1 Instrument Identification – Testing Positions

Whenever stirrer or vessel positions are referenced in this document the following numbering applies. Only at PTWS 120D/S and 820D: there are two ways of orientation when setting up a PTWS 120/820 instrument. Mark below in which mode of orientation the instrument is installed:

Section 2.1.1 PTWS 120D/S:

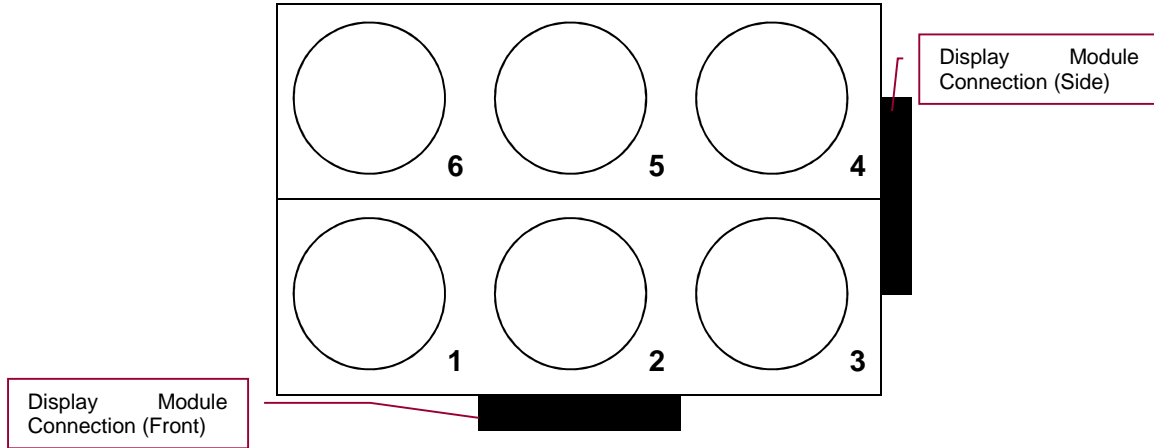


Figure 1: Vessel Numbering of the PTWS 120D/S Orientation A

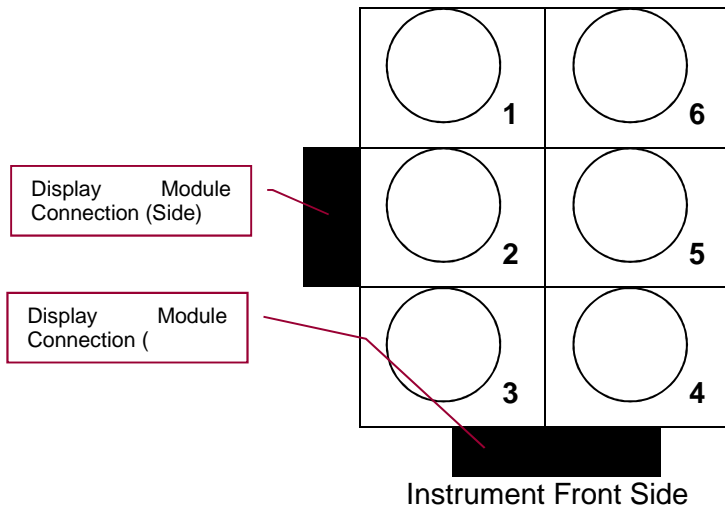


Figure 2: Vessel Numbering of the PTWS 120D/S – Orientation B

Mode of Orientation	OK	NA
Mode A - 3 x 2		
Mode B - 2 x 3		

Performed by: _____ Date: _____
 Signature MM/DD/YYYY

Section 2.1.2 **PTWS 820D:**

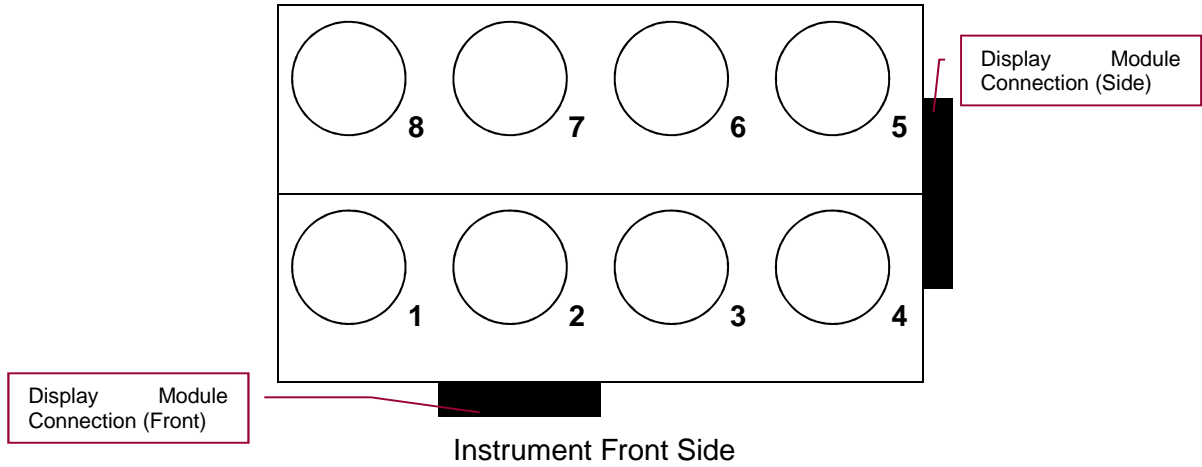


Figure 3: Vessel Numbering of the PTWS 820D – Orientation A

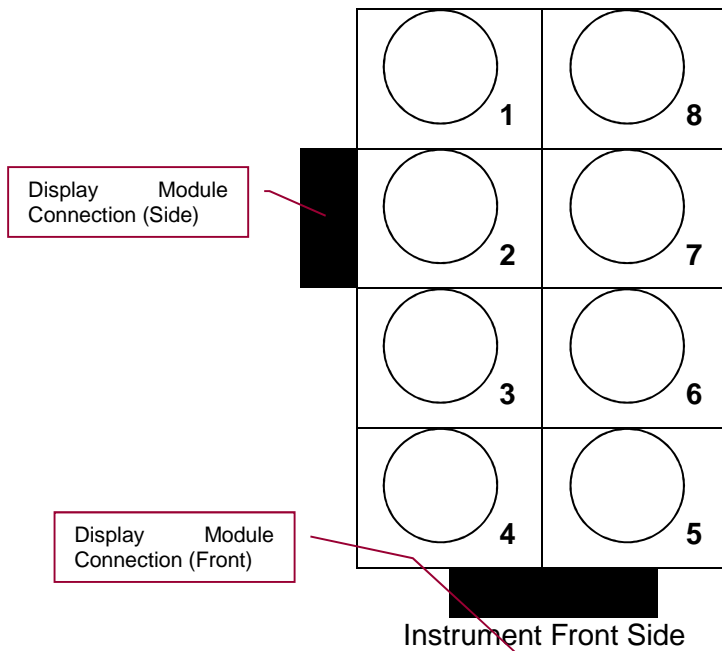


Figure 4: Vessel Numbering of the PTWS 820D – Orientation B

Mode of Orientation	OK	NA
Mode A - 4 x 2		
Mode B - 2 x 4		

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 2.1.3 **PTWS 620:**

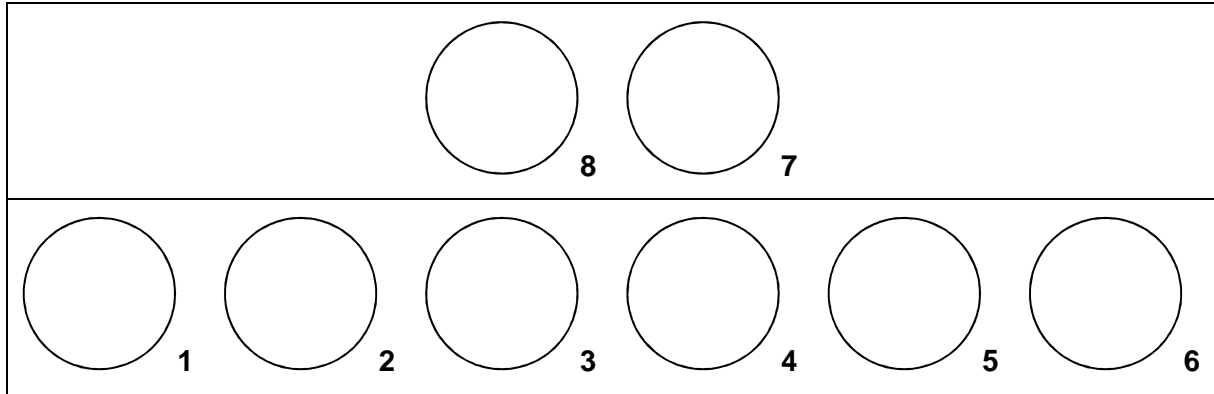


Figure 5: Vessel Numbering of the PTWS 620

Section 2.1.4 **PTWS 1220/D620:**

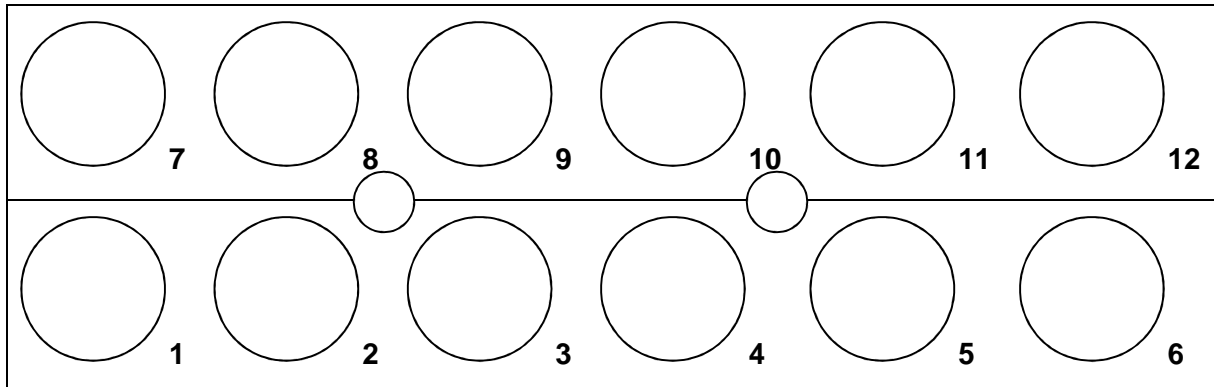


Figure 6: Vessel Numbering of the PTWS 1220 and PTWS D620

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 3.0 Personnel Identification

Installation Engineer (1): _____
Name (print) Initials

Signature Date (MM/DD/YYYY)

Installation Engineer (2): _____
(optional) Name (print) Initials

Signature Date (MM/DD/YYYY)

Installation Engineer (2): _____
(optional) Name (print) Initials

Signature Date (MM/DD/YYYY)

Approved by: _____
Name (print) Initials

Signature Date (MM/DD/YYYY)

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 3.1 Required Qualification Equipment and Materials Identification

Part-No.	Description	Serial No.	rec.	N/A	miss.
30-31005	Digital laser tachometer				
30-31006	Digital tachometer				
30-31007	Digital thermometer				
10-61000	Stop watch				
30-31080	Digital goniometer				
307-1205	Precision dial gauge for SWT				
30-31206	Axial Position testing Gauge SCT				
46-01810	Digital caliper				
315-0200	Depth adjustment ball, 25mm				

Performed by: _____
Signature

Date: _____
MM/DD/YYYY

Section 3.2 End User Information

Company Name: _____

Address: _____

Department: _____

Location: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature

MM/DD/YYYY

Section 4.0 Operation Qualification Procedure

This section provides the operational procedure to qualify the instrument. Complete each subsection as described.

For more detailed information on the general usage of the instrument refer to the instruction manual. Make sure to go through the instruction manual before starting the OQ procedure to be familiar with the usage of the instrument beforehand.

Section 4.1 Level the Instrument.

Measure the level of the Instrument at 2 directions (Front to Back and Right to Left. Max allowed Tolerance is +/- 0.2°

Front to Back

pass	fail	N/A

Right to Left

pass	fail	N/A

Section 4.2 Fill Up the Water Bath

Fill up the water bath using de-ionized water up to the “max. level” mark. Prime the pump system.

pass	fail	N/A

Section 4.3 Perform Power Up Test

Turn on the PTWS x20 instrument using the mains power switch on the back side of the pump module. The display lights up. Check that the display is evenly illuminated and that there are no dead pixels or other display defects.

pass	fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.4 Verify Instrument Serial Number

Note the serial number displayed on the start screen of the instrument. Check that this serial number corresponds to the serial number printed on the type plate on the back of the instrument.

pass	fail	N/A

Section 4.5 Verify Installed Firmware Version

Note the firmware version displayed on the start screen of the instrument. Check that this firmware version corresponds to the version noted in the supplied QC report for this instrument.

pass	fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.6 Login as Administrator

To use the instrument you need to login first. Select "Login" from the start screen by touching the button and select "Administrator". Enter the default password "1234" for the Administrator and confirm with "Enter".

pass	fail	N/A

Section 4.7 Perform Lift Operation and Key Test

To test the correct lift function, select "**LIFT CONTROL**" from the main menu. The lift control menu will open. Use the <Reference>-key to move the lift to the upper home position. Keep your finger on the button until the lift stops automatically in the highest position and became green. Then move the lift down into the lower home position by touching the <down arrow>-key. Again, keep your finger on the button until the lift stops automatically in the lowest position.

pass	fail	N/A

Section 4.8 Enter Bath Control Menu

Select "**BATH CONTROL**" to control the pump and temperature settings.

In the "**HEATER STATUS**", the target temperature of the water bath is shown in the first line. In the middle line the actual temperature inside the water bath is displayed. In the third line the actual temperature of the hand sensor is displayed.

pass	fail	N/A

Section 4.9 Perform Pump Test

In the "**BATH CONTROL**" menu, select "**PUMP OFF**" to turn off the pump. Select "**PUMP ON**". Check that the pump turns on and that there is water flowing.

pass	fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.10 Check Pump Flow

The water bath is filled with ionized water. The pump is turned on. In case there is no water flow detected an error message will appear on the screen.

Use a graduated cylinder holding at least 4 liters and the calibrated digital stop watch. Clamp the short tube from the pump outlet to the bath inlet to interrupt the water flow. Use the quick disconnect on the pump outlet to disconnect the tube. Pull the male part of the quick disconnect out of the tube. Use an additional tube of approx. 50cm length (or something similar) and insert the male part of the quick disconnect there. Put the other end of the additional tube into the water bath through a vessel opening after taking out the vessel there. Insert the end with the male part of the quick disconnect into the quick disconnect. The water is now flowing again from the pump into the water bath. Now, take the end of the additional tube out of the water bath and collect the water flowing from the pump in the cylinder for 30 seconds. Check how much water is collected in the cylinder and double the amount to calculate the flow rate per minute. In case no large enough cylinder is available, use a smaller cylinder and reduce the collection time accordingly, then again calculate the flow rate per minute. Check that the result is within the given range. Put the tubing back in as it was before this test and fill up the water bath again. Put the vessel back into position. Document the flow rate below:

Time	Multiplied	Equals	Range	Measured	pass	fail	N/A
	by	1 minute	2.0 – 5.0l/min				

Section 4.11 Temperature Setting

In the “**BATH CONTROL**” menu, select “**SET TEMP**” and enter 37.0°C as target temperature. Select “**HEATER ON**” to start the heating system. Check that the temperature starts rising.

pass	fail	N/A

Section 4.12 Install Paddle Stirrer Assembly

Move the lift into the upper home position. The stirrers are still switched off.

In case the instrument is supplied with paddles, attach the paddle blade adapters to the drive shafts. The drive shafts are numbered. Install the assembled stirrers into their corresponding spindle positions.

pass	Fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.13 Install Basket Stirrer Adapter (alternatively)

In case the instrument is supplied with baskets, unscrew the paddle blade adapters from the drive shafts if necessary. If already installed, the drive shafts may remain in the spindle positions. Attach the baskets and basket adapters to the drive shafts. The drive shafts are numbered. Install the assembled stirrers into their corresponding spindle positions and attach the stirrer clamp screws if necessary.

pass	fail	N/A

Section 4.14 Install Other Tool (alternatively)

In case the instrument is supplied with another type of tools, install them according to the type and usage of the tool.

pass	fail	N/A

Section 4.15 Attach the Stirrer Shaft Clamp Screws

Attach each black stirrer shaft clamp screw onto each stirrer drive shaft to hold them in position. Tighten the clamp screw by hand so that the assembled stirrers remain in place in their spindle positions.

pass	fail	N/A

Section 4.16 Indicate the Installed Stirring Tool Set

Indicate the installed stirring tool set:

Installed stirring tool					
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other	

Section 4.17 Install the Dissolution Vessels

The lift is still in the upper home position. The stirrers are still switched off.

Place the dissolution vessels into their positions using the corresponding holes in the water bath cover. Follow the numerical order. Using three adjustment discs mounted on the underside of the water bath cover, each dissolution vessel can be individually centered towards the stirrer. By using the fixing screws in the water bath cover, the adjustment discs can be turned and the vessel is thus adjusted in its position inside the hole in the water bath cover.

pass	fail	N/A

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.18 Check the Stirrer Immersion Depth

Drive the instrument head into the upper home position. Place a depth adjustment ball into each dissolution vessel. Either use a certified depth adjustment ball or check the dimensions of the depth adjustment ball before the test with the certified digital caliper. Note dimensions of the depth adjustment balls below and confirm that they are within the given range.

Loosen the stirrer shaft clamps on top slightly but make sure the tools remain in position. Drive the instrument head into the (lower) working position. Gently push each stirring shaft downwards until it touches the depth adjustment ball. Gently push each stirrer shaft clamps downwards until it rests into position and fix the position using the locking nut of the stirrer shaft clamps. The immersion depth is now equal to the dimensions of the depth adjustment ball. Tolerance is 25+/-2mm.

Position	Target	Range	Measured	pass	fail	N/A
1	25.00mm	23.00 – 27.00mm				
2	25.00mm	23.00 – 27.00mm				
3	25.00mm	23.00 – 27.00mm				
4	25.00mm	23.00 – 27.00mm				
5	25.00mm	23.00 – 27.00mm				
6	25.00mm	23.00 – 27.00mm				
7	25.00mm	23.00 – 27.00mm				
8	25.00mm	23.00 – 27.00mm				
9	25.00mm	23.00 – 27.00mm				
10	25.00mm	23.00 – 27.00mm				
11	25.00mm	23.00 – 27.00mm				
12	25.00mm	23.00 – 27.00mm				

Section 4.19 Check the Stirrer Speed

The stirring tools are assembled and installed in their positions. They are held in place by the locking screw at the stirrer shaft clamps on top.

Set the target stirring speed as per the tables below. Check the stirring speed at each stirrer using the calibrated tachometer. Measure approx. 15 seconds after turning on the stirrers. Measure for 1 minute. Document the displayed values below. Check that all results are within the given range (this range represents a tolerance of +/-1rpm for Speeds under 150rpm and +/-2rpm over 150rpm):

Position	Target	Range	Measured	pass	fail	N/A
1	50 RPM	49 – 51 RPM				
2	50 RPM	49 – 51 RPM				
3	50 RPM	49 – 51 RPM				
4	50 RPM	49 – 51 RPM				

Performed by: _____ Date: _____
Signature MM/DD/YYYY

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Position	Target	Range	Measured	pass	fail	N/A
5	50 RPM	49 – 51 RPM				
6	50 RPM	49 – 51 RPM				
7	50 RPM	49 – 51 RPM				
8	50 RPM	49 – 51 RPM				
9	50 RPM	49 – 51 RPM				
10	50 RPM	49 – 51 RPM				
11	50 RPM	49 – 51 RPM				
12	50 RPM	49 – 51 RPM				
Position	Target	Range	Measured	pass	fail	N/A
1	100 RPM	99 – 101 RPM				
2	100 RPM	99 – 101 RPM				
3	100 RPM	99 – 101 RPM				
4	100 RPM	99 – 101 RPM				
5	100 RPM	99 – 101 RPM				
6	100 RPM	99 – 101 RPM				
7	100 RPM	99 – 101 RPM				
8	100 RPM	99 – 101 RPM				
9	100 RPM	99 – 101 RPM				
10	100 RPM	99 – 101 RPM				
11	100 RPM	99 – 101 RPM				
12	100 RPM	99 – 101 RPM				
150 RPM						
1	150 RPM	148 – 152 RPM				
2	150 RPM	148 – 152 RPM				
3	150 RPM	148 – 152 RPM				
4	150 RPM	148 – 152 RPM				
5	150 RPM	148 – 152 RPM				
6	150 RPM	148 – 152 RPM				
7	150 RPM	148 – 152 RPM				
8	150 RPM	148 – 152 RPM				
9	150 RPM	148 – 152 RPM				
10	150 RPM	148 – 152 RPM				
11	150 RPM	148 – 152 RPM				

Performed by: _____ Date: _____

Signature

MM/DD/YYYY

Pharma Test Apparatebau AG
Operation Qualification (OQ)

Position	Target	Range	Measured	pass	fail	N/A
12	150 RPM	148 – 152 RPM				

Section 4.20 Check the Stirrer and Basket Wobble

Check the stirrer wobble (run out) of each stirring tool, use the SWT wobble meter with the precision dial gauge.

Indicate the tested stirring tool:

Tested stirring tool						
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other		

Set the target stirring speed as per the table below. Measure the wobble at each stirring tool 2cm above the top of the paddle blade or rim of the basket. Document the displayed values below. Check that all results are within the given range: The Maximum allowed Wobble is 1mm.

Position	Target	Range	Measured	pass	fail	N/A
1	25 RPM	0.00 – 1.00mm				
2	25 RPM	0.00 – 1.00mm				
3	25 RPM	0.00 – 1.00mm				
4	25 RPM	0.00 – 1.00mm				
5	25 RPM	0.00 – 1.00mm				
6	25 RPM	0.00 – 1.00mm				
7	25 RPM	0.00 – 1.00mm				
8	25 RPM	0.00 – 1.00mm				
9	25 RPM	0.00 – 1.00mm				
10	25 RPM	0.00 – 1.00mm				
11	25 RPM	0.00 – 1.00mm				
12	25 RPM	0.00 – 1.00mm				

Performed by: _____ Date: _____
Signature MM/DD/YYYY

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Next tested stirring tool							
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other		NA	

Position	Target	Range	Measured	pass	fail	N/A
1	25 RPM	0.00 – 1.00mm				
2	25 RPM	0.00 – 1.00mm				
3	25 RPM	0.00 – 1.00mm				
4	25 RPM	0.00 – 1.00mm				
5	25 RPM	0.00 – 1.00mm				
6	25 RPM	0.00 – 1.00mm				
7	25 RPM	0.00 – 1.00mm				
8	25 RPM	0.00 – 1.00mm				
9	25 RPM	0.00 – 1.00mm				
10	25 RPM	0.00 – 1.00mm				
11	25 RPM	0.00 – 1.00mm				
12	25 RPM	0.00 – 1.00mm				

Copy this page in case more tools are supplied. Attach and number the copies.

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.21 Check the Vessel/Stirrer Shaft Centricity

Set the target stirring speed as per the table below. Check the vessel/stirrer shaft centricity. Use the centering cover, the SCT instrument or any suitable gauge. Document the values below. Check that all results are within the given range. The Stirrer should not be more than 1mm out of the Centre.

Indicate the installed stirring tool:

Installed stirring tool					
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other	

Check that all results are within the given range:

Position	Range	Measured	pass	fail	N/A
1	-1.00 – 1.00mm				
2	-1.00 – 1.00mm				
3	-1.00 – 1.00mm				
4	-1.00 – 1.00mm				
5	-1.00 – 1.00mm				
6	-1.00 – 1.00mm				
7	-1.00 – 1.00mm				
8	-1.00 – 1.00mm				
9	-1.00 – 1.00mm				
10	-1.00 – 1.00mm				
11	-1.00 – 1.00mm				
12	-1.00 – 1.00mm				

Performed by: _____ Date: _____
Signature MM/DD/YYYY

Section 4.22 Check the Temperature Inside the Water Bath

Check that the target temperature is set to the target value from the table below. Check that the heater is turned on. Wait until the water bath is fully warmed up and temperature equilibrium has been reached at the target temperature. If using non pre-heated medium this will take approx. 90 minutes from the time the heater was turned on. Measure the temperature inside the water bath, midway between the water surface and the bottom of the water bath. Measure in the middle position of each vessel opening. Take out one vessel after another for each measurement and return it into its position after the measurement. Lock down the vessel again after returning it. Use the calibrated thermometer for the measurements. Measure for at least 30 seconds at each position and document the displayed temperatures below. Check that all results are within the given range. The Tolerance is 37 +/-0,5°C

Position	Target	Range	Measured	pass	fail	N/A
1	37.0°C	36.5 - 37.5°C				
2	37.0°C	36.5 - 37.5°C				
3	37.0°C	36.5 - 37.5°C				
4	37.0°C	36.5 - 37.5°C				
5	37.0°C	36.5 - 37.5°C				
6	37.0°C	36.5 - 37.5°C				
7	37.0°C	36.5 - 37.5°C				
8	37.0°C	36.5 - 37.5°C				
9	37.0°C	36.5 - 37.5°C				
10	37.0°C	36.5 - 37.5°C				
11	37.0°C	36.5 - 37.5°C				
12	37.0°C	36.5 - 37.5°C				

Performed by: _____

Date: _____

Signature

MM/DD/YYYY

Section 4.23 Check the Vessel Temperature

Check that the target temperature is set and the heater is turned on. Fill each vessel with 900ml of water. Install and cover each vessel. Lock down the vessel again after returning it. Wait until the medium inside the vessels has reached temperature equilibrium at the target temperature. If non pre-heated medium is used, this may take up to 90 minutes as water bath temperature will also drop when the cold vessels are installed. Measure the temperature inside the vessels, midway between the water surface and the bottom of the vessel. Measure in the middle position of each vessel opening. Place the external temperature sensor of the instrument together with the certified thermometer (you may bind both sensors together using a rubber band or similar) into the vessel. Depending on environmental temperature it might be necessary to increase the water bath temperature up to 37.8°C to receive 37.0°C inside the vessels. Measure in one vessel after another. Measure for at least 30 seconds at each position and document the displayed temperatures below. Check that all results are within the given range. The Tolerance is 37 +/- 0,5°C

Position	Target	Range	Measured	pass	fail	N/A
1	37.0°C	36.5 - 37.5°C				
2	37.0°C	36.5 - 37.5°C				
3	37.0°C	36.5 - 37.5°C				
4	37.0°C	36.5 - 37.5°C				
5	37.0°C	36.5 - 37.5°C				
6	37.0°C	36.5 - 37.5°C				
7	37.0°C	36.5 - 37.5°C				
8	37.0°C	36.5 - 37.5°C				
9	37.0°C	36.5 - 37.5°C				
10	37.0°C	36.5 - 37.5°C				
11	37.0°C	36.5 - 37.5°C				
12	37.0°C	36.5 - 37.5°C				

Section 4.24 Shaft Verticality

Check the Verticality of the Shaft at 2 opposed positions (Pos). Use a certified digital Caliper. The Tolerance is 90 +/- 0,5°.

Shaft	Target	Range	Measured	pass	fail	N/A
1 Pos 1	90°	89,5° - 90,5°				
1 Pos 2	90°	89,5° - 90,5°				
2 Pos 1	90°	89,5° - 90,5°				
2 Pos 2	90°	89,5° - 90,5°				
3 Pos 1	90°	89,5° - 90,5°				
3 Pos 2	90°	89,5° - 90,5°				

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4 Pos 1	90°	89,5° - 90,5°				
4 Pos 2	90°	89,5° - 90,5°				
5 Pos 1	90°	89,5° - 90,5°				
5 Pos 2	90°	89,5° - 90,5°				
6 Pos 1	90°	89,5° - 90,5°				
6 Pos 2	90°	89,5° - 90,5°				
7 Pos 1	90°	89,5° - 90,5°				
7 Pos 2	90°	89,5° - 90,5°				
8 Pos 1	90°	89,5° - 90,5°				
8 Pos 2	90°	89,5° - 90,5°				
9 Pos 1	90°	89,5° - 90,5°				
9 Pos 2	90°	89,5° - 90,5°				
10 Pos 1	90°	89,5° - 90,5°				
10 Pos 2	90°	89,5° - 90,5°				
11 Pos 1	90°	89,5° - 90,5°				
11 Pos 2	90°	89,5° - 90,5°				
12 Pos 1	90°	89,5° - 90,5°				
12 Pos 2	90°	89,5° - 90,5°				

Section 4.25 Vessel Verticality

Check the Verticality of the Vessel. The measurement is performed at 2 Positions at about 0° and 90°.

The Tolerance is 90 +/- 1°.

Vessel	Target	Range	Measured	pass	fail	N/A
1 Pos 1	90°	89° - 90°				
1 Pos 2	90°	89° - 90°				
2 Pos 1	90°	89° - 90°				
2 Pos 2	90°	89° - 90°				
3 Pos 1	90°	89° - 90°				
3 Pos 2	90°	89° - 90°				
4 Pos 1	90°	89° - 90°				
4 Pos 2	90°	89° - 90°				
5 Pos 1	90°	89° - 90°				
5 Pos 2	90°	89° - 90°				

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Operation Qualification (OQ)

6 Pos 1	90°	89° - 90°				
6 Pos 2	90°	89° - 90°				
7 Pos 1	90°	89° - 90°				
7 Pos 2	90°	89° - 90°				
8 Pos 1	90°	89° - 90°				
8 Pos 2	90°	89° - 90°				
9 Pos 1	90°	89° - 90°				
9 Pos 2	90°	89° - 90°				
10 Pos 1	90°	89° - 90°				
10 Pos 2	90°	89° - 90°				
11 Pos 1	90°	89° - 90°				
11 Pos 2	90°	89° - 90°				
12 Pos 1	90°	89° - 90°				
12 Pos 2	90°	89° - 90°				

Section 4.26 Vibration

Check the Vibration on the Top of the Waterbath and the Head of Dissolution Tester. The Vibration should not be over 0,1Mil

Position	Target	Range	Measured	pass	fail	N/A
Waterbath	<= 0,1Mil	0,0 – 0,1 Mil				
Head	<= 0,1Mil	0,0 – 0,1 Mil				

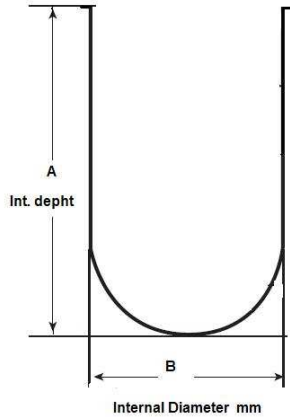
Performed by: _____ Date: _____
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MM/DD/YYYY

Section 4.27

Check Vessel Dimensions

Pharma Test certifies that the supplied USP/EP 1l vessels, the stirring shafts and adapters have been carefully tested and that the dimensions comply with the valid EP/USP/JP Pharmacopoeia and or ISO norm.

Vessel Specifications of the Valid USP <711> and EP <2.9.3> Monograph:



Norm	A (mm)	B (mm)	Nominal Volume	Material
USP/EP	160 – 210	98 -106	1,000ml	Glass or other transparent material
USP	380 - 300	98 – 106	2,000ml	Glass or other transparent material

Measure and note the dimensions below:

Pos.	Vessel SN	A (mm)	B (mm)	Nominal Volume (ml)	Material	pass	fail	N/A
1					Borosilicate Glass			
2					Borosilicate Glass			
3					Borosilicate Glass			
4					Borosilicate Glass			
5					Borosilicate Glass			
6					Borosilicate Glass			
7					Borosilicate Glass			
8					Borosilicate Glass			
9					Borosilicate Glass			
10					Borosilicate Glass			
11					Borosilicate Glass			
12					Borosilicate Glass			

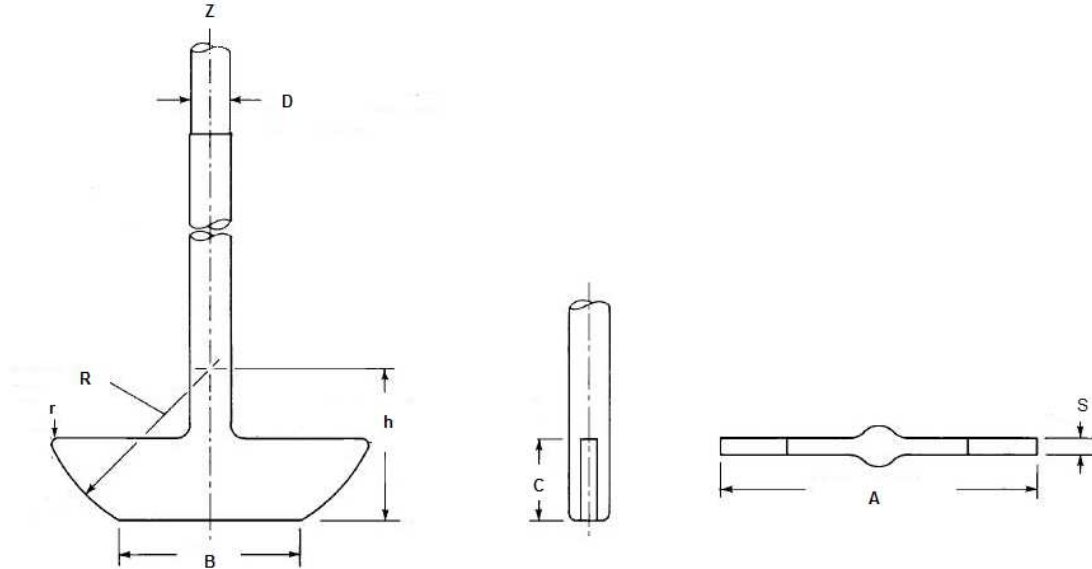
Copy this page in case more vessels are supplied. Attach and number the copies.

Performed by: _____ Date: _____
 Signature MM/DD/YYYY

Section 4.28 Check Paddle Dimensions

Pharma Test certifies that the supplied USP/EP 11 vessels, the stirring shafts and adapters have been carefully tested and that the dimensions comply with the valid EP/USP/JP Pharmacopoeia and or ISO norm.

Paddle Specifications of the Valid USP <711> and EP <2.9.3> Monograph:



Norm	A (mm)	B (mm)	C (mm)	D (mm)	S (mm)
USP/EP	74.0 – 75.0	41.0 – 43.0	18.5 – 19.5	9.4 – 10.1	3.0 – 5.0

Measure and note the dimensions below:

Pos.	1	2	3	4	5	6	7	8	9	10	11	12	pass	Fail	N/A
Paddle SN															
Shaft SN															
A															
B															
C															
D															
S															

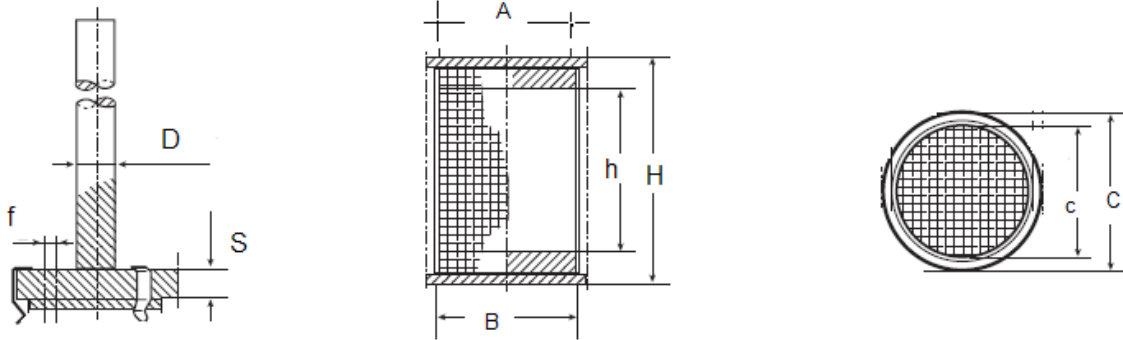
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Section 4.29 Check Basket Dimensions

Pharma Test certifies that the supplied USP/EP 11 vessels, the stirring shafts and adapters have been carefully tested and that the dimensions comply with the valid EP/USP/JP Pharmacopoeia and or ISO norm.

Basket Specifications of the Valid USP <711> and EP <2.9.3> Monograph:



Norm	A (mm)	B (mm)	C (mm)	c (mm)	D (mm)	S (mm)	f (mm)	H (mm)	h (mm)
USP/EP	19.2 – 21.2	NA	22.0 – 28.0	19.2 – 21.2	9.4 – 10.1	4.6 – 5.6	1.5 – 2.5	34.0 – 40.0	26.0 – 28.0

Measure and note the dimensions below:

Pos.	1	2	3	4	5	6	7	8	9	10	11	12	pass	Fail	N/A
Basket SN															
Adapter SN															
Ring SN															
Shaft SN															
A															
B															
C															
c															
D															
S															
F															
H															
h															

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Section 4.30 Select a Method and Start a Test

To use the instrument you need to select an existing method. The instrument is delivered with a factory set method named "PTAG". Select this method to perform one automated test sequence. Follow the on-screen instructions. The instrument will automatically start pump and heater. You need to drive the instruments head into the operating position by hand. When the lift drive is in its operating position and all test parameters have been met, press <DROP TABLET> and the stirrers will start. The programmed sampling intervals will start.

pass	fail	N/A

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Section 5.0 Result and Comments

The instrument has passed the operation qualification procedure.

Yes

No

Check yes if all tests have passed. In case one or more tests failed check no and document the reason for the failure on this report. In this case the operation qualification has to be repeated once the reason for failure has been eliminated.

Comments

This completes the operation qualification of the PTWS x20 instrument.

Performed by: _____ Date: _____
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Approved by: _____ Date: _____
Signature MM/DD/YYYY

Released by: _____ Date: _____
Signature MM/DD/YYYY